POC accepted 3/26/08 B. Cavanagh Letter sent to admin.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	NVN2048ASC	A. BUILDING _____ B. WING _____	03/07/2008

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SURGICAL ARTS SURGERY CENTER	5411 KIETZKE LANE RENO, NV 89511

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 00	INITIAL COMMENTS This Statement of Deficiencies was generated as the result of a focused State Licensure survey conducted at your facility on 3/7/08. The survey was conducted using Nevada Administrative Code (NAC) 449, Surgical Centers for Ambulatory Patients. Findings and conclusions of any investigation by the Health Division shall not be construed as prohibiting any criminal or civil investigations, actions, or other claims for relief that may be available to any party under applicable federal, state, or local laws. The following regulatory deficiencies were identified.	A 00	The focus survey under State Licensure as conducted by Barbara Cavanagh, RN, CCM and Maggie Lizarraga, RN, COHN was well received by Surgical Arts Surgery Center. Below you will find comments supporting our plan for corrective action for each finding. Attached you will also find amplifying information that detailed processes have been put into place to prevent further occurrences as noted in order to insure a safe environment for ambulatory surgery care. RECEIVED MAR 24 2008 BUREAU OF LICENSURE AND CERTIFICATION CARSON CITY, NEVADA	
A 10	NAC 449.980 Administration The governing body shall ensure that: 7. The center adopts, enforces and annually reviews written policies and procedures required by NAC 449.971 to 449.996, inclusive, including an organization chart. These policies and procedures must: (a) Be approved annually by the governing body. This Regulation is not met as evidenced by: Based on record review and interview, it was determined that the governing body failed to review the facility's written policies and procedures annually. Findings include: On 3/7/08, the facility's Infection Control Policies and Procedures Manual was reviewed. The	A 10	A10. In accordance with NAC 449.971 and NAC 449.996, the Governing conducted a meeting with thorough review of the Medical Executive minutes and recommendations. The Governing Board approved the Standards, Policies and Procedures as presented by the Medical Executive Committee. The Board also reviewed all policy binders that included at a minimum: Quality Assurance, Safety, Infection Control, External Regulatory Standards, Accreditation 2008 Guidelines and Policies and Procedures. The cover page of each binder reflects approval from the Governing Board consistent with the mandate noted above. The Governing Board also recognized and approved modifications to policies and	

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A 10	Continued From page 1 manual contained documentation that the governing body last approved the policies and procedures on 9/18/99. The administrator reported the governing body was planning to review the policies and procedures at their next meeting in March 2008. Severity: 1 Scope: 3	A 10	procedures in support of direct efforts to prevent infection control outbreaks as recently discovered in Las Vegas. The Agenda and Minutes of the Governing Board along with revised policies including anesthesia notices as drafted by the Medical Director are attached for reference. A154 The following actions have been taken to correct the sterilization documentation and deficiencies noted in the core and sub-sterile rooms: <u>Bio-testing Verification.</u> The Biological testing log has been revised to accurately identify each sterilizer, the biological test frequencies and core personnel conducting and verifying the tests. Bio testing is performed weekly on the autoclave #3 in the core and daily for each flash autoclave #'s 1&2 s in the sub-sterile rooms. Effective immediately bio tests will be documented daily for each autoclave tested. Copies of the bio test binder cover, inside page and testing documentation is attached for reference. <u>Core Competencies</u>: During any absences of our staff core technician, orientation protocols have been improved to insure proper training of operating room technicians and or nurses that may perform duties in the CORE. The orientation includes at a minimum, Core Sterilization procedures, running biological tests for the 3 autoclaves and 2 steris units. The emphasis on comprehensive orientation is infection control and safety. With the recent turnover of operating room technicians, all newly hired techs and	
A154	NAC 449.9895 Sterilization 4. The efficiency of the method of sterilization used must be checked not less frequently than once each month by bacteriological tests. Records of the results of these tests must be maintained by the center for at least 1 year. This Regulation is not met as evidenced by: Based on observation, interview and policy review it was determined that the facility failed to assure by documentation that the biological testing was conducted in accordance with the facility's policy and procedure for 3 of 3 autoclave sterilizers. Findings include: The facility had three autoclave sterilizers. One was located next to Operating Room #1 and was referred to Substerilizer #1. The second autoclave was located between Operating Rooms #2 and #3 and was referred to Substerilizer #2. The third autoclave was located in the "Core." Review of the facility's BioSign Biological Indicator Culturing Test Record book revealed numerous gaps in the documentation that biological testing was conducted on the three autoclave sterilizers in accordance with the facility policy beginning January 2008. For example, the documentation indicated testing was done on	A154		

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A154	Continued From page 2 1/2/08 and 1/7/08 for sterilizers #1, #2, and #3. The documentation of testing on 2/8/08, 2/26/08, 2/27/08, 2/28/08, 2/29/08, 3/3/08, and 3/4/08 did not include a reference to the sterilizer tested. The record book failed to reveal evidence of reference to which sterilizers were #1, #2, or #3. The employee who was primarily assigned to the Core was not available for interview on 3/7/08. Interview with the Clinical Director on 3/7/08, while observing the sterilization procedures, revealed that Substerilizers #1 and #2 were to have biological testing conducted daily and testing was to be conducted every Monday for the autoclave (#3) in the Core. Review of the facility policy/procedure titled , "Sterilization Policy's and Practices Core Procedure revealed that a Bio test was to be run on Autoclave #3 every Monday at the second load and bio's were to be run on Autoclaves #1 and #2 in the substerile rooms at the end of the shift. A second interview with the Clinical Director revealed that the facility's Core Technician resigned on 12/31/07. Prior to leaving she had conducted an inservice for three surgical technician in regard to the sterilization policies and procedures. One of those employees was currently at the facility. Two surgical technicians who had sterilization experience at other facilities had recently been hired. One employee had worked at the facility per diem two days a week beginning on 6/20/07 and was hired full time on 2/11/08. This employee was the principal Core technician. The second recently hired employee started working at the facility on 3/3/08. Severity: 1 Scope: 3	A154	existing techs have be oriented and demonstrated competencies with core activities as noted above. Infection Control. To proactively prevent against any transmission of infections such as Hepatitis C, the Medical Director an anesthesiologist drafted several documents attached hereto in collaboration with the other Medical Directors during a meeting held on March 17, 2008. The emphasis of the notice is to bring attention to the proper handling and cleaning of laryngoscope blades, endotracheal tubes and proper protocols associated with the use of multiple dose vials. These documents will remain a work in progress until all corrective measures are standardized across the board with both anesthesia groups and enforced by each surgical site facility. Pharmacy, Múltiple Dose Vials. The State of Nevada Board of Pharmacy has been in contact with Surgical Arts Surgery Center and our Pharmacy Consultant. The Board informed us that modifications to standards and protocols concerning multiple dose vials will be disseminated soon. Once the pharmacy consultant receives the updates from the Nevada Board of Pharmacy, we will be implementing the changes at Surgical Arts in short order. Surgical Arts Surgery Center stands ready to provide safe and compassionate care to each of our patients.	

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If deficiencies are cited, an approved plan of correction must be returned within 10 days after receipt of this statement of deficiencies.

SURGICAL ARTS SURGERY CENTER
ORIENTATION TO THE CORE

The purpose of Core Orientation is to insure that all personnel that work in the core become thoroughly familiar with all infection control policies and fully understand the sterilization requirements for autoclaves the steris units to include proper maintenance of biological testing for each sterilization device.

The orientation will include safety precautions concerning the handling sharp objects and use of proper protective gear to include goggles to prevent from eye splash contamination.

I have reviewed the policies noted below and received training on core procedures with demonstrated competencies:

- Core Sterilization
- Running Biological for Steam Autoclaves
- Running Biological tests for Steris Autoclaves.

_____ _____
Employee / Title Date

_____ _____
Training Instructor / Title Date

SURGICAL ARTS SURGERY CENTER
Policy/Procedure

Date reviewed: 3/10/08

APPLICABLE TO: Clinical Staff

TITLE: Core Sterilization

PURPOSE:
The purpose of this policy is to establish approved practices that will assist in ensuring that all reusable medical devices undergo sterilization process under the best possible conditions for maximum safety. This policy also outlines procedures for daily routine in the Core for monitoring the sterilization equipment. This policy ensures the elimination of risks to patients and healthcare personnel from cross-contamination by a potentially pathogenic microorganism.

EVERY MORNING:
- Turn on Sonic
- Heat Sealer
- Autoclave #3

DAILY TESTS:

First thing in morning
- Run Bowie in Autoclave #3
- Run Bio's in Autoclave #1 & #2 in Substerile Rooms

At end of shift
- Run diagnostic cycle in both Steris machines for early morning cases.
- Wipe down all surfaces with Cavicide, mop floor and dump trash.
- Clean flush tank
- Turn off autoclave #3, sonic and heatsealer

EVERY MONDAY:
- Run Bio's in Streris followed by diagnostic
- Run a test Bio in #3 2nd load.
- Make sure all tapes are signed off
- Make sure a load card is in every load with all documentation
- Wipe down outside of autoclave with stainless cleaner.
- Clean interior of autoclave with descaler.
- Clean out hopper with bleach or Cavicide

EVERY TWO WEEKS:
- Change milk; 1 part milk/ 5 parts water
- Check stock for reordering

CLEAR DETAILED DOCUMENTATION IS MANDATORY ON EVERY PROCEDURE

SURGICAL ARTS SURGERY CENTER **Date reviewed: 3/10/08**
Policy/Procedure **Page 1 of 1**

APPLICABLE TO: Clinical Staff

TITLE: Running Biologicals for Steris

PURPOSE: All scopes, camera's and light cord equipment has potential to be a vector in the transmission of microorganisms. Proper cleaning, disinfections and or sterilization of this equipment can reduce the risk of infection to the patient.

POLICY: Every Monday the following procedure is followed:

1. Run a Bio Test in *Steris* Machine #1 and #2.
   - A. The Bio Tests are kept in the refrigerator in the pharmacy.
   - B. Use (3) vials and (3) test strips (do not touch test strips with bare hands it will affect the test)
   - C. Label vials as follows:
     1. "C" for control
     2. #1 for *Steris* one
     3. #2 for *Steris* two
   - D. Place one test strip in the vial labeled control
     1. Date and initial
     2. Place in incubator
   - E. Run the other two test strips in each of the *Steris* Machines (1&2) on regular cycle.
   - F. When the cycle is complete:
     1. Place the test strips in each vial
     2. Initial and date each vial
     3. Place in incubator for 48 hours
   - G. Record status of tests in the *Steris* log books (Log books are 9"x12" size located on the *Steris* machines)

SURGICAL ARTS SURGERY CENTER **Date reviewed: 3/10/08**
Policy/Procedure **Page 1 of 1**

APPLICABLE TO: Clinical Staff

TITLE: Running Biologicals for Steam Autoclaves

PURPOSE: All surgical equipment has potential to be a vector in the transmission of microorganisms. Proper cleaning, disinfections and or sterilization of this equipment can reduce the risk of infection to the patient.

POLICY: **EVERY MONDAY** the following procedure is performed:

1. Place a fresh control vial in the incubator.
2. Run one Bio in autoclave #1, #2, and #3
3. When Bio's are complete:
   A. Check the label on the vial to make sure the color strip on the label has changed from pink to brown.
      * **PINK LABEL ALERT:**
      1. If there is a load, **DO NOT** use the load.
      2. Rewrap and run the load again
      3. If no load, rerun test with new vial.
      4. Allow the Bio to cool for 15 minutes before crushing it.
   B. On loads that have chanced color, initial and date.
   C. Push the cap down and place in the incubator
   D. Make sure to crack the internal vial in the ambule crusher built into the incubator.
   E. Bio results checked at 48 hours during the week and first thing on Monday for Friday's run.
      ***NOTE:** The control should turn yellow indicating growth. The Bio Tests that were run should stay red.

      IF THE BIO'S TURN YELLOW
      1. Alert the Clinical Director
      2. Cross reference batch for any surgeries that instruments may have been used on.
      3. Recall any unused instruments to run again.
      4. Run another test load to determine if the integrity of indicator was compromised.
      5. If the test is still yellow, call *Steris*
      6. Call any Physicians who's cases may have been affected.

EVERY DAY the following procedure is performed:

1. Run a Bio in autoclave #1 & #2 and follow the same protocol above.

* **NOTE:** **Always run a bio with implants**

2. With each run autoclave tape is checked, initialed by circulating nurse and patient sticker is placed on the back of the tape.
3. At the end of the day the orderly checks the tapes for signatures and tapes are record in the autoclave envelope for the week.

Auto Clave
Auto Clave
Auto Clave

SUI
SUR

BIOSIGN

BIOLOGICAL INDICATOR CULTURING TEST RECORD

DATE	STERILIZER NO.	LOAD NO.	CYCLE GAS	CYCLE STEAM	CYCLE TIME	CYCLE TEMP	INCUBATION DATES IN	INCUBATION DATES OUT	RESULTS TEST	RESULTS CONTROL	INITIAL
3/10	2			X			3/10 8:00	3/12 8:00	+ -	+ -	KB
3/10	3			X			3/10 8:00	3/12 8:00	+ -	+ -	KB
3/11	1			X			3/11 8:00	3/13 8:00	+ -	+ -	KB
3/11	2			X			3/11 8:00	3/13 8:00	+ -	+ -	KB
3/12	1			X			3/12	3/14	+ -	+ -	KB
3/12	2			X			3/12	3/14	+ -	+ -	KB
3/13	1			X			3/13 8:00	3/17 8:00	+ -	+ -	KB
3/13	2			X			3/13 8:00	3/17 8:00	+ -	+ -	KB

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BIOSIGN

BIOLOGICAL INDICATOR CULTURING TEST RECORD

DATE	STERILIZER NO.	LOAD NO.	CYCLE GAS	CYCLE STEAM	CYCLE TIME	CYCLE TEMP	INCUBATION DATES IN	INCUBATION DATES OUT	RESULTS TEST	RESULTS CONTROL	INITIAL
3/14	1			X			3/14 8:00	3/17 8:00	+ -	+ -	KB
3/14	2			X			3/14 8:00	3/17 8:00	+ -	+ -	KB
3/17	3C						3/17 8:00	3/24 8:00	+	+	KB
3/17	1			X			3/17 8:00	3/19 8:00	+	+ -	KB
3/17	2			X			3/17 8:00	3/19 8:00	+	+ -	KB
3/17	3 C			X			3/17 8:00	3/19 8:00	+	+ -	KB
3/18	1			X			3/18 8:00	3/20	+	+ -	KB
3/18	2			X			3/18 8:00	3/20	+	+	KB

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1-2-3 Autoclaves

12/1 good

TEMPLATE

- o Clave #1 **Located in sub-sterile one**
- o Clave # 2 **Located in sub-sterile two and three**
- o Clave #3 **Located in the Core**

SURGICAL ARTS

Biological Monitoring Record

AUTOCLAVES

1-2-3

GETINGE Castle

Getinge/Castle, Inc.
1777 East Henrietta Road
Rochester, New York 14623-3133
Tel 800-950-9912
Fax 800-950-2570

1-2-3 Autoclaves

RECEIVED
MAR 24 2008
BUREAU OF LICENSURE AND CERTIFICATION CARSON CITY, NEVADA

12/1 1 good

TEMPLATE

uto Clave #1 **Located in sub-sterile one**
uto Clave # 2 **Located in sub-sterile two and three**
uto Clave #3 **Located in the Core**

SURGICAL ARTS

BIOSIGN

BIOLOGICAL INDICATOR CULTURING TEST RECORD

DATE	STERILIZER NO.	LOAD NO.	CYCLE GAS	CYCLE STEAM	CYCLE TIME	CYCLE TEMP	INCUBATION DATES IN	INCUBATION DATES OUT	RESULTS TEST	RESULTS CONTROL	INITIAL
9/6	1								+ -	+ -	
9/6	2								+ -	+ -	
9/7	1								+ -	+ -	
9/9	2								+ -	+ -	
9/10	1								+ -	+ -	
9/10	2	1		X			9/10	9/12	+ -	+ -	A
9/10	3	653 9				9/10			+ -	+ -	
									+ -	+ -	

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BIOLOGICAL INDICATOR CULTURING TEST RECORD

DATE	STERILIZER NO.	LOAD NO.	CYCLE GAS	CYCLE STEAM	CYCLE TIME	CYCLE TEMP	INCUBATION DATES IN	INCUBATION DATES OUT	RESULTS TEST	RESULTS CONTROL	INITIAL
3/19	1			X			3/19 8:00	3/21 8:00	+ -	+ -	KB
3/19	2			X			3/19 8:00	3/21 8:00	+ -	+ -	KB
3/19	3			X			3/19 8:00	3/21 8:00	+ -	+ -	KB
3/20	1			X			3/20	3/20	+ -	+ -	KB
3/20	2			X			3/20	3/20	+ -	+ -	KB
3/20	3			X			3/20	3/20	+ -	+ -	KB
									+ -	+ -	
									+ -	+ -	

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DATE	STERILIZER NO.	LOAD NO.	CYCLE GAS	CYCLE STEAM	CYCLE TIME	CYCLE TEMP	INCUBATION DATES IN	INCUBATION DATES OUT	RESULTS TEST	RESULTS CONTROL	INITIAL
									+ -	+ -	
									+ -	+ -	
									+ -	+ -	
									+ -	+ -	
									+ -	+ -	
									+ -	+ -	
									+ -	+ -	
									+ -	+ -	

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SURGICAL ART SURGERY CENTER
ATTENTION
PHYSICIANS AND NURSES

On Monday March 17, 2008 the Medical Directors for the Ambulatory Surgery Centers located in the Reno/Sparks area met with the idea of providing some consistency for policies and procedures involving infection control issues within those centers. These include the following:

1. Medications. No medications from outside surgical facilities are allowed in the center. If there is a specific medication that an individual would like to have on Formulary, discuss this with either the Medical Director or the Nursing Supervisor. If the request is reasonable, every effort to obtain that Medication will be made. Anyone that is found bringing in outside medications will receive one written warning. A second violation will result in suspension from the Staff at the surgery center, which would necessitate appearance before the Medical Executive committee for reinstatement of privileges.

2. Briefcases/backpack/tackle boxes in the operating rooms. We realize that there are certain items carried by anesthesiologists as well as surgeons that are important for patient care. However, due to the problems with outside medications as well as laryngoscope blades that are carried in then, they pose a problem. It was agreed that briefcases or backpacks could be carried into the room. However, by doing so you the will willfully consent to those items undergoing inspection by either the Medical Director or the nursing supervisor/charge nurse. If you will not allow that inspection, do not bring that briefcase/backpack into the operating room. Leave it in a sub sterile area outside the operating room.

3. Laryngoscopes. Currently all facilities supply the basic laryngoscopes and blades that are most commonly used by anesthesia. We also recognize that there are some individual preferences as to types of blades such as MAC 3.5 IV (improved view) or an English Miller 2, etc. as well as the need for certain devices used in airway rescue. If anesthesia desires to use these devices, it is the policy then to notify your circulating nurse prior to the beginning of the case. Your blade will undergo sterilization via a Steris process and will be available prior to the start of the surgery. This means that it is a good idea to arrive early or to identify the need for such early on in the pre-anesthesia process.

   Additionally, we will be happy to Steris your rescue blades and package them in peel packs for you. This will allow you to demonstrate that your equipment has been disinfected to facility standards when traveling to another facility.

   Please do not bring in the same MAC or Miller blades that we supply and either ask to use them or have them sterilized. The idea is to allow equipment that is other wise not carried in be available to help you give the best care.

   Laryngoscope blades provided by the center. Our blades will not be routinely stocked in the anesthesia machine drawers. The additional blades will be located in the Pharmacy/equipment room, and kept in individual peel packages. Please identify your needs to your nurse prior to the beginning of your case and those blades will be made available for you. After you use them, place them in the basin designated for

the dirty laryngoscopes. A new blade will be provided for you between cases. Any questions regarding this should be directed to our Medical Director.

4. Surgical Attire. No surgical attire including scrubs from other facilities will be allowed into the operating room suites. It is okay to wear those items into the facility. However, a set of scrub clothing from Surgical Arts must be worn in the operating room. This policy includes all physicians, first assistants, or other assistants. This standard is applicable to all SASC employees as well.

5. Needles and Syringes. It really does not need to be repeated, but will be done so to emphasize the severity of this policy. **NEEDLES AND SYRINGES ARE SINGLE USE ITEMS AND ARE NOT TO BE REUSED FORM PATIENT TO PATIENT.** We are all aware of the problems occurring down in Las Vegas. However, a similar situation occurred in New York and in Oklahoma involving an anesthesiologist and a nurse anesthetist reusing syringed from one patient to another resulting in multiple patients contracting Hepatitis C. Both of those practitioners lost their licenses. The reuse of syringes is strictly against the standards and guidelines of The American Society of Anesthesiologists.

6. Single dose vials. We are all attempting to obtain as may of our medications as possible in single dose vials. However, not all meds can be obtained in this manner of packaging. Additionally, we are waiting for direction from the Nevada State Board of Pharmacy. During the interim, we will be following the standard USP protocol: Once a medication has the lid removed, it will be labeled with the date and initials of the person labeling the container. Aseptic technique would be used to draw any medication from the vial. If there is no date or initial on the vial/bottle, then discard the container. After 28 days, that container will be discarded. Vials when opened should immediately be labeled by the Anesthesiologist or the nurse assigned to that room.

We appreciate everyone's willingness to cooperate with new implementations. Part of what we are doing is also protecting your own personal license as well as ours. Please, if there are any questions about any of our policies, please fell free to contact our Medical Director or Clinical supervisor.
Thank You,

Edward M. Draper II, MD. 19 Mar 2008
Medical Director Date